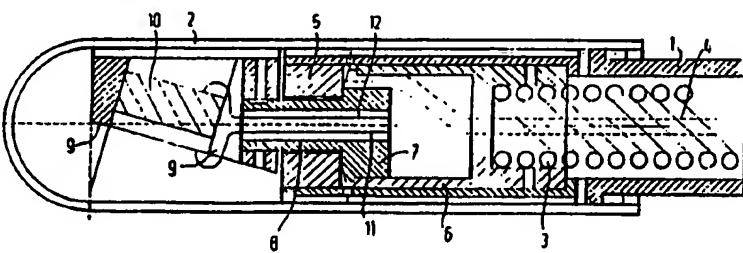




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/NL90/00057</p> <p>(22) International Filing Date: 26 April 1990 (26.04.90)</p> <p>(30) Priority data: 8901084 28 April 1989 (28.04.89) NL</p> <p>(71) Applicant (<i>for all designated States except US</i>): DU-MED B.V. [NL/NL]; Overschieseweg 54, NL-3044 EG Rotterdam (NL).</p> <p>(72) Inventors; and</p> <p>(75) Inventors/Applicants (<i>for US only</i>) : JONGELING, Johannes, Mattheus [NL/NL]; Foulkeslaan 47, NL-2625 PZ Delft (NL). LANCEE, Charles, Theodoor [NL/NL]; Westeinde 17, NL-3466 NK Waarder (NL).</p> <p>(74) Agent: SMULDERS, Th., A., H., J.; Vereenigde Octrooibureaux, Nieuwe Parklaan 107, NL-2587 BP The Hague (NL).</p>		<p>(81) Designated States: AT (European patent), BE (European + patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent), US.</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>	
<p>(54) Title: AN INTRA-ARTERIAL DEVICE</p> 			
<p>(57) Abstract</p> <p>An intra-arterial device comprising a catheter having at an end to be inserted into an artery a tip or part (7-10) which is movable relative to the rest of the catheter, and comprising means (3) for causing said part or tip to rotate at a desired speed relative to the catheter and relative to operating means and control apparatus at or near the control end of the catheter, an optical fibre (4) being provided in or connected with the catheter, which fibre extends up to the vicinity of said rotatable tip or part, and adjacent to or in the tip or part marking means (5) being provided, which can be observed through the optical fibre at the control end of the catheter, either the fibre (4) or the marking means (5) being arranged to move along with the rotatable tip or part.</p>			

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Title: An intra-arterial device

The invention relates to an intra-arterial device for the examination or treatment of blood vessels, comprising a catheter having at an end to be inserted into an artery a tip which is movable relative to the rest of the catheter, and 5 further comprising means for causing said tip to rotate at a desired speed relative to the catheter and relative to operating means and control apparatus at or near the control end of the catheter.

Such a device is known from Dutch patent application 10 No. 8700632. In the known device the fixed part of the catheter adjacent to the rotatable tip is provided with a transducer and the tip is provided with a mirror in slanting position relative to the transducer (Fig. 3). Through the rotation of the tip with the mirror high-frequency 15 ultrasonic vibrations emitted by the transducer are emitted in various directions along a rotating path and the echoes are received in a similar way, so that a picture of a section of the area around the catheter tip can be formed.

Obviously it is possible to provide the rotating catheter 20 tip with the transducer, in which case a mirror is not required. The above publication already shows a rotating transducer, although it is positioned just behind the otherwise stationary tip of the catheter (Fig. 2).

The tip is usually rotated by means of a drive motor 25 positioned at the control end of the catheter, which motor is connected to the tip through a flexible shaft extending

through the catheter. The shaft must be flexible because the catheter, when in operation, is inserted into the artery system of a patient to be examined and must be able to follow all the bends and curves of that system. A problem arises here 5 in that the exact position of the catheter tip is no longer known. Even with a flexible shaft which has been designed with as much stiffness in torsion as possible, the possibility exists that some torsion occurs along the entire length of the shaft, so that the position of the shaft at the motor end does 10 not provide accurate information on the position of the tip at the other end of the shaft.

Furthermore, disturbances in the rotation behaviour of the tip may occur as a result of, for example, friction occurring in the catheter tube or the tip bearing. The result 15 of all this is that in processing the echo signals from the tip of the vibrations emitted by the transducer, which processing is usually done by computer, a signal cannot be attributed accurately to a particular location, so that an inaccurate or even distorted picture is formed of the area 20 around the tip. In fact, the effect of the above phenomena on a display picture will be that within a circle of 360° the sound bundles travel "too fast" around the circumference in one sector and too slowly" somewhat further on. This will certainly give a distorted picture, which can be problematic, 25 especially for certain uses of the device, such as its use in removing obstructions in the artery by means of spark erosion. In that application it is of major importance that the spark

erosion is performed at the position of the obstruction. For this purpose this position should be known exactly.

Furthermore, a distorted picture is problematic for a correct diagnostic interpretation of the pictures.

5 The invention aims to provide a device in which the above problem of the accurate location is solved. This aim is achieved with a device in which an optical fibre is incorporated into or connected with the catheter, which fibre extends up to the vicinity of the rotatable tip or rotatable 10 part, and adjacent to or in that tip or part marking means are provided, which can be observed through the optical fibre at the control end of the catheter, either the fibre or the marking means being arranged to move along with the rotatable tip or rotatable part. In this way, according to the 15 invention, the exact position, or at least the angular position of the rotating part relative to the non-rotating part of the catheter end can be determined at any moment. If, in computer processing of the echo signals of the transducer, the information concerned is also fed to the computer, the 20 computer can always picture each signal in the correct place, so that always a true image is formed.

In a suitable embodiment of the device according to the invention the optical fibre is incorporated in the means for causing the tip of the catheter to rotate, so that the end of 25 the fibre adjacent to the tip rotates along with the tip, the marking means being fixed on, or forming part of, a fixed section of the catheter adjacent to the tip.

Regardless of whether the fibre rotates and the marking means are stationary, or whether the fibre is stationary and the marking means are connected to the rotating tip, according to the invention the marking means are preferably formed by a

5 substantially disc-shaped or ring-shaped body with a surface which is virtually perpendicular to the shaft of the catheter at that point, opposite which surface is the end of the fibre, in which the body rotates when the fibre is stationary and the other way round, so that when the tip rotates the fibre end

10 describes a circular movement along the surface and in which markings have been applied to the surface in the path described thereon by the fibre tip. Suitably, in that embodiment the markings consist of a number of circularly arranged reflecting segments positioned at regular intervals.

15 For a correct location it is desirable that in a suitable place in the series of regularly arranged segments an irregularity is provided. Such an irregularity may consist of the absence of a segment in the suitable place. This absent segment then serves as a point of reference in the circular

20 path. Of course it is also possible that the irregularity consists of a different shape of the segment at that point, compared to the shape of the other segments.

It has to be noted that a device for examination of cavities by means of ultrasound, comprising an optical fibre

25 in combination with marking means, is known per se from French Patent Application No. 2,467,583. Said known device, however, is of the endoscope type, to be used for examination of

intestines and like larger cavities. Therefore it is rather heavy and cannot be used as an intra-arterial device.

The invention will now be described with reference to the drawings, in which:

5 Fig. 1 is a cross-sectional view of the end of the catheter with a rotatable tip in one embodiment of the device according to the invention; and

Fig. 2 is an illustration of a suitable system of markings for use in the device according to Fig. 1.

10 Fig. 1 schematically shows a cross-section of the end of the catheter in an embodiment of the device according to the invention. Catheter tube 1 is sealed at that end with an end cap 2 made of a suitable material. The material of end cap 2 should be permeable to the ultrasonorous radiation from the
15 transducer at the end of the catheter, and obviously also to the echoes to be received by the transducer. Extending through catheter tube 1 is a flexible, rotatable shaft 3, which is or can be connected at the other end of the catheter (not shown) to a drive motor to cause shaft 3 to rotate in catheter tube
20 1. Extending in the centre of shaft 3, whose structure, for that matter, is irrelevant to the present invention, is an optical fibre 4. In the flexible, rotatable shaft 3 are also incorporated suitable electrical wires to feed the transducer in the catheter tip and to carry the signals back from the
25 transducer to the processing means at the other end of the catheter.

Adjacent to the end of catheter tube 1 a disc 5 is installed in it, which is directed perpendicularly to the shaft of tube 1. Disc 5 is fixed to catheter tube 1. The rotatable shaft 3 terminates a certain distance short of disc 5. Secured to the end of shaft 3 is a flange which is connected to a bushing 6. Bushing 6 has an outside diameter slightly smaller than the inside diameter of catheter tube 1, so that bushing 6 can rotate smoothly within tube 1. In the front end of bushing 6 is fixed a cylindrical body 7 with a reduced section 8, which body 7,8 is provided with a central throughbore. The reduced section 8 of cylinder 7, extends through a central opening in the fixed disc 5. The dimensions of the several parts are, for instance, such that section 8 of cylinder 7 is journalled, as it were, in the opening in disc 5.

Secured to the reduced section 8 of cylinder 7, beyond the opening in disc 5, is a holder 9 for transducer 10. Electrical wires and signal wires 11 and 12 leading to the front electrode surface and the back electrode surface, respectively, of the ceramic transducer plate of transducer 10 extend through the throughbore in body 7 and the clearance in bushing 6 to the front end of the rotatable shaft 3, through which shaft 3 they are passed further through the catheter.

At the front end of the rotatable shaft 3 the optical fibre 4 is passed laterally away from the centre of the shaft and deflects to terminate, through a suitable throughbore through a section of cylinder 7 which is adjacent to the outer

circumference of cylinder 7, on the outside of the reduced part 8 just in front of one of the main surfaces of disc 5. When in operation, the catheter tip made up of parts 6 to 10 rotates along with the rotatable shaft 3, since those parts 5 are fixedly secured to shaft 3. The end face of the laterally deflected optical fibre 4 thus describes a circular path along the opposed surface of fixed disc 5. In this path suitable markings are provided on the surface of disc 5. These markings can be detected through the optical fibre. Since the optical 10 fibre is fixedly secured to the rotary tip at the catheter end, in this way the position of the catheter tip can be connected unambiguously to the position of the fixed catheter tube 1. In this way the position of the transducer relative to the fixed catheter tube end is always known. The markings on 15 the fixed disc 5 can, for instance, be detected by shining light on them through the optical fibre 4 and passing the reflected light through the fibre to the other end of the catheter, where suitable processing means can be provided. If the processing means comprise a computer, the marking signals 20 can be connected therein, by means of software which can simply be designed by one skilled in the art, to the echo signals from the transducer. In this way a true image of the surroundings of the catheter tip can be formed which is not distorted by unobserved torsional or frictional decelerations 25 and/or accelerations of the catheter tip.

Fig. 2 shows a top plan view of the fixed disc 5 at the end of the catheter tube 1, viewed from the side where the

front face of the optical fibre 4 is located. On disc 5 a system of markings 13 is provided, which are arranged in a circular path. The system of markings comprises, for instance, a series of reflecting segments 13 which are arranged at 5 regular intervals from each other in a circle. The area between each pair of successive segments is not reflecting. If light is directed to the circular path through the optical fibre 4 moving along the circle of segments 13, consecutive reflection signals will be received through the fibre. At one 10 point in the circular path a segment has been left out. This lacking segment 14 causes an interruption in the regular series of reflection signals and can therefore serve as a point of reference. In this way the location of the end of the optical fibre and hence the position of the rotary tip of the 15 catheter relative to the fixed disc and thus the fixed catheter tube can be determined at any time.

The reflecting segments 13 can be made in any way desired. When the fixed disc is made of glass the ring of segments can be formed by optically etching a chromium layer 20 formed on the glass disc, according to the desired pattern. It is also possible to fix optically reflecting nickle segments on a layer of polyimide on disc 5 or on a disc 5 made of polyimide.

It will be clear that it does not make any difference for 25 a correct location whether disc 5 is fixed relative to the catheter tube and the optical fibre rotates along with the tip, or whether the fibre is fixedly arranged in the catheter

tube and the markings rotate along with the tip. The construction described above, however, is preferred for its compact structure.

To give an impression of the dimensions of the device
5 according to the invention it can be observed that in an embodiment realised in practice disc 5 had a diameter of 1.255 mm, with a central opening of 0.5 mm. Segments 13 each had a height of 0.1 mm, and the number of segments in a circular path on the disc was 99. The rotary tip of the catheter was
10 surrounded by an end cap 2 with a length of 6 mm and a diameter of 1.67 mm, and the catheter tube had a diameter of 1.3 mm.

It will further be clear that other embodiments are possible within the scope of the invention. It is, for
15 example, possible to realise the marking by using a cylindrical body adjacent to the end of the catheter, which body rotates along with the rotary part, and is provided with suitable code segments on its inside surface. In that case the markings extend virtually parallel to the longitudinal axis of
20 the catheter, and the optical fibre should then be positioned in such a way that the end for observing the markings is directed radially, unless a suitable mirror or prism is positioned between the fibre end and the markings.

CLAIMS

1. An intra-arterial device for the examination or treatment of, for example, blood vessels, comprising a catheter having at an end to be inserted into an artery a tip or part which is movable relative to the rest of the catheter, and further comprising means for causing said part or tip to rotate at a desired speed relative to the catheter and relative to operating means and control apparatus at or near the control end of the catheter, characterized in that an optical fibre is provided in or connected with the catheter, which fibre 5 extends up to the vicinity of said rotatable tip or part, and adjacent to or in the tip or part marking means are provided, which can be observed through the optical fibre at the control end of the catheter, either the fibre or the marking means being arranged to move along with the rotatable tip or part.
- 10 2. An intra-arterial device according to claim 1, characterized in that the optical fibre is incorporated in the means for causing the tip to rotate, so that the end of the fibre adjacent to the tip rotates along with the tip, the marking means being fixed on, or forming part of, a fixed section of the catheter adjacent to the tip.
- 15 3. An intra-arterial device according to claims 1 or 2, characterized in that the marking means are formed by a substantially disc-shaped or ring-shaped body with a surface which is virtually perpendicular to the shaft of the catheter 20 at that point, the end of the fibre being positioned opposite said surface, in which the body rotates when the fibre is stationary and the other way round, so that when the tip rotates the fibre end describes a circular movement along the surface, and in which markings have been applied to the 25 surface in the path described thereon by the fibre tip.
- 30 4. An intra-arterial device according to claim 3, characterized in that the markings consist of a number of

circularly arranged reflecting segments positioned at regular intervals.

5. An intra-arterial device according to claim 4, characterized in that in a suitable place in the series of regularly arranged segments an irregularity is provided.
6. An intra-arterial device according to claim 5, characterized in that the irregularity consists of the absence of a segment in the suitable place.

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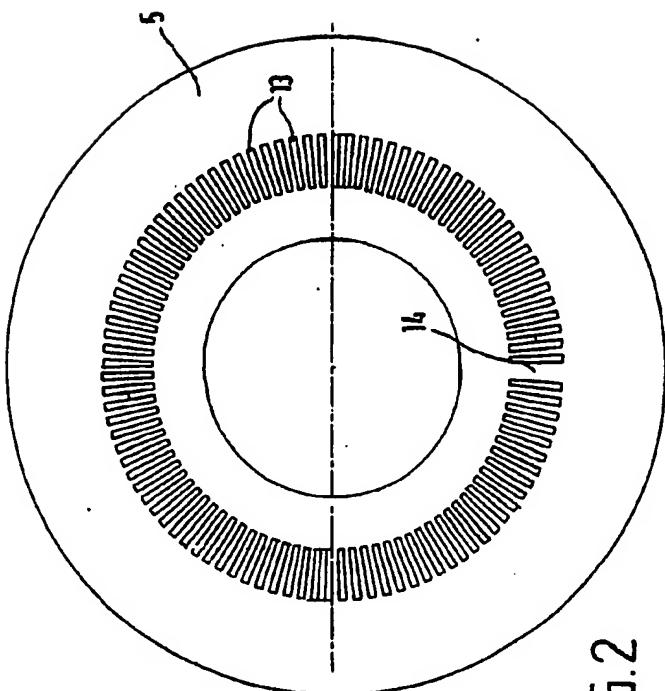
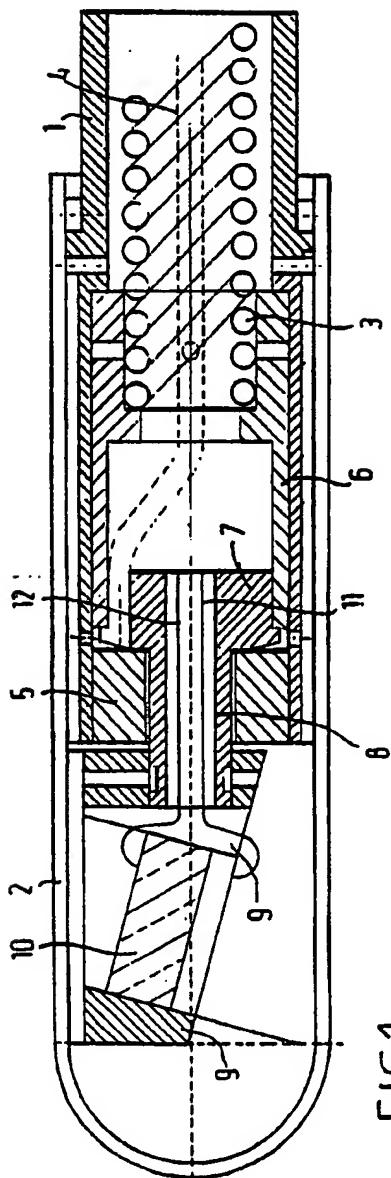
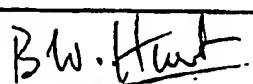


FIG. 2

INTERNATIONAL SEARCH REPORT

International Application No

PCT/NL 90/00057

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ¹⁰		
According to International Patent Classification (IPC) or to both National Classification and IPC Int.C1. 5 A61B1/00 ; A61B8/12 ; G10K11/00 ; G01D5/34		
II. FIELDS SEARCHED		
Minimum Documentation Searched ¹¹		
Classification System	Classification Symbols	
Int.C1. 5	A61B ; G10K ; G01D	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ¹²		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹³		
Category ¹⁴	Citation of Document ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	FR,A,2467583 (OLYMPUS OPTICAL CO. LTD.) 30 April 1981 see page 7, line 22 - page 9, line 4 see page 21, lines 10 - 29 see page 24, lines 10 - 23; figures 1-5, 11, 13 (cited in the application) ---	1
A	GB,A,2082769 (OLYMPUS OPTICAL CO. LTD.) 10 March 1982 see page 4, lines 32 - 84 see page 5, line 115 - page 6, line 44; figures 1, 2, 9, 10 ---	2-6
X	GB,A,2082769 (OLYMPUS OPTICAL CO. LTD.) 10 March 1982 see page 4, lines 32 - 84 see page 5, line 115 - page 6, line 44; figures 1, 2, 9, 10 ---	1
A	DE,A,2948182 (HEWLETT-PACKARD CO.) 10 July 1980 see page 9, lines 1 - 14; figures 1, 4, 5 ---	2-5
A	DE,A,2948182 (HEWLETT-PACKARD CO.) 10 July 1980 see page 9, lines 1 - 14; figures 1, 4, 5 ---	1, 6
		-/-
<p>* Special categories of cited documents :¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"I" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
07 AUGUST 1990	12.09.90	
International Searching Authority EUROPEAN PATENT OFFICE	Signature of Authorized Officer HUNT B.W. 	

Form PCT/ISA/210 (second sheet) (January 1985)

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED) FROM THE SECOND SHEET		
Category	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	NL,A,8700632 (STICHTING BIOMEDICAL ENGINEERING) 17 October 1988 see claims 1-9; figures 1-3 (cited in the application) ---	1

ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.

NL 9000057

SA 36743

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR-A-2467583	30-04-81	JP-A- 57052444 JP-A, B, C56060546 JP-A, B, C56060547 DE-A, C 3039523 GB-A, B 2063474 US-A- 4391282	27-03-82 25-05-81 25-05-81 07-05-81 03-06-81 05-07-83
GB-A-2082769	10-03-82	None	
DE-A-2948182	10-07-80	US-A- 4266125 JP-A- 55085218	05-05-81 27-06-80
NL-A-8700632	17-10-88	None	

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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IN THE CLAIMS:

Claims 1-25. (Cancelled)

26. (Currently Amended) An operating device controlled with a treatment instrument comprising:

a n operating navigation system for generating an icon to which control of the operating device is assigned;

an observation apparatus having a panel on which an observationmedical image and the icon generated by the operating navigation system are displayed;

a first marker marked on the observation apparatus;

a second marker marked on the treatment instrument;

a position detector for detecting a position of the first marker to get a position of the icon, and for detecting a position of the second marker to get a tip position of the treatment instrument, so that an operator can control the operating device by touching the icon with the tip of the treatment instrument.

27. (Currently Amended) The operating device according to claim 26, wherein the icon is displayed as an image having no parallax even if it is viewed with the right eye or viewed with the left eye.

28. (Currently Amended) The operating device according to claim 26, further comprising:

at least one image projector for projecting the observationmedical image and the icon on the panel of the observation apparatus to display them thereon.

29. (Currently Amended) The ~~operating~~ device according to claim 26, wherein the panel of the observation apparatus is used in sterilized conditions.

30. (Currently Amended) The ~~operating~~ device according to claim 26, further comprising:

an image projector for the right eye of an observer for projecting the observation~~medical~~ image for the right eye on the panel of the observation apparatus; an image projector for the left eye of the observer for projecting the observation~~medical~~ image for the left eye on the panel of the observation apparatus, wherein the observation~~medical~~ image for the right eye and the observation~~medical~~ image for the left eye have a parallax for each other, and the panel of the observation apparatus has an optical power so that the observer can observe the observation~~medical~~ image as a three-dimensional image.

31. (Currently Amended) The ~~operating~~ device according to claim 30, wherein the panel of the observation apparatus has a Fresnel mirror surface.

32. (Currently Amended) An ~~operating~~ device controlled with a treatment instrument comprising:

an ~~operating~~ navigation system for generating an icon to which control of the ~~operating~~ device is assigned; an observation apparatus having a panel on which an observation ~~medical~~ image and the icon generated by the ~~operating~~ navigation system are displayed;

a position detector for detecting each position of the icon and the treatment instrument held by an operator, so that the operator can control the operating device by touching the icon with the tip of the treatment instrument.

33. (Currently Amended) A method for controlling an operating device with a treatment instrument comprising:

generating an icon to which control of the operating device is assigned;
displaying the icon on a panel with an observationmedical image;
detecting each position of the icon and a treatment instrument held by an operator;

performing the control assigned to the icon when a touching of the icon with a tip of the treating instrument is detected.

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